AT&T
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Basking Ridge, NJ 07920-1650

July 22, 1993

Mr. Jerome E, Dennis, Chief
Light Products Branch (HFZ-312)
Office of Compliance
Center for Devices & Radiological Health
Food & Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Dear Mr. Dennis:

Re: FDA 21 CFR Part 1040 Notice of Intent
to Amend Performance Standard

AT&T commends the Food & Drug Administrationis intent to amend the Performance Standard for Laser Products (21 CFR 1040). AT&T has been proactive in supporting ANSI and IEC efforts to harmonize laser safety standards while vigilant to the requirement of maintaining public safety. AT&T appreciates the accumulation of new biological data since 1985, and is pleased that this data has been considered in the standards-setting process.

AT&T views this Notice of Intent as a positive effort in the areas of harmonization, recognition of biological evidence, and practicality associated with compliance and product safety. AT&T supports the FDA's intention on these points:

Jerry
This should go to OSK (& Docketa?) to file in NOI comments.
This issues on reporting have already been addressed.

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Harmonization

Harmonization with ANSI and IEC will serve to increase the competitiveness of U.S. products around the world. The globalization of markets has made it imperative for U.S. corporations to conform with global standards. The harmonization, especially with the IEC, will make conformance less complicated and more cost effective. In this respect, AT&T supports amendments 12 and 13 which propose that IEC-825 warning and explanatory labels be accepted as alternatives to current labels and non-interlocked housing labels.

Biological Data

AT&T supports the FDA's recognition of new biological evidence, since 1985, in proposing amendments 1, 4, 5, 6, & 7. While most of these amendments could also be categorized under "harmonization," AT&T wants to emphasize and support the conclusions of the members of FDA, IEC and ANSI committees based on the interpretation of the increasing body of research that advances the safe use of lasers.

AT&T agrees with FDA's proposals to increase the AEL in the spectral range from 500 to 1400 nanometers for emission durations of 10 seconds or longer; to reduce the AEL of Class 1 for repetitively pulsed lasers; to expand the wavelength *range* for "eye safe" infrared laser radiation; to amend the AEL of the classes of laser products; and to revise the measurement parameters for radiant power or energy

Practical Considerations

AT&T agrees that some requirements in the current Performance Standard do not impact public safety but may place a burden on the manufacturer. since some of these amendments also bring FDA in accord with IEC and ANSI, we support the inclusion of amendments 2,3,8,9,10, 14, and 15.

We recognize the practical importance of reducing the emission durations for the Classification of Class I laser products that emit visible or infrared laser radiation not intended for human exposure; the addition of a Class IIIa for the ultraviolet and infrared regions; the relaxation of the radiation levels for safety interlocks; the relaxation of the requirement for emission indicators and beam attenuators; the addition of the requirement for visible indicators for remote laser apertures for Class IIIb and IV systems; the simplification of the requirements for labels for noninterlocked and defeatable interlocked protective housings; and the simplification of the user information requirements.

Amendments 11, 16, 17, 18, and 19 do not currently apply to our business so we decline to comment on these at this time

Also, AT&T requests that a section be included in the amendment to exempt from reporting certain law-power laser products. This section would condense and clarify provisions set forth in Laser Notices 36, 41 and 42 and other notices as applicable. Such inclusion would make available such information to the broad audience it is intended for, and reduce misunderstandings associated with the administration of the regulation.

We appreciate the opportunity to comment on these amendments to the laser product performance standard. If you need any follow-up comments, please call our Corporate Laser Safety Officer, Ron Petersen, on (908) 582-6442.

Leon Mitrani

Leon Mitrani
Member of the
Technical Staff